NAT'L INST. OF STAND & TECH
A11106 460313
NIST PUBLICATIONS
REFERENCE

NISTIR 7214

Weights and Measures Division Quality Manual For Proficiency Testing and Interlaboratory Comparisons

Gust, Jeff C.
Harris, Georgia L.

NIST
National Institute of Standards and Technology
Technology Administration, U.S. Department of Commerce

QC
100
U56
#7214
2005

NISTIR 7214

Weights and Measures Division Quality Manual For Proficiency Testing and Interlaboratory Comparisons

Gust, Jeff C. (contract)
Quametec Corporation

Harris, Georgia L.
Weights and Measures Division
Technology Services

March 2005

U.S. DEPARTMENT OF COMMERCE
Carlos M. Gutierrez, Secretary
TECHNOLOGY ADMINISTRATION
Phillip J. Bond, Under Secretary of Commerce for Technology
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
Hratch G. Semerjian, Acting Director

TABLE OF CONTENTS

TABLE OF CONTENTS iii
ABSTRACT v
INTRODUCTION 7
Scope 7
Document Retention 7
References 7
Definitions 9
1. ADMINISTRATION 10
1.1. Quality System & Policy 10
1.2. Organization and Management 11
1.3. Roles and Responsibilities 12
1.4. Collaboration and Subcontracting 13
1.5. Fees 14
1.6. Policy for Participation 14
1.7. Document Control 15
1.8. Request, Tender or Contract Review 16
1.9. Procurement of Services and Supplies 17
1.10. Client Feedback 17
1.11. Control of Nonconforming Activities and Corrective Action 18
1.12. Preventive Action 19
1.13. Records 19
1.14. Internal & External Audits 20
1.15. Management Review 21
1.16. Management Staffing and Training 21
1.17. Collusion and Falsification of Results 22
1.18. Data Processing Equipment 22
2. PLANNING 24
2.1. Technical Protocol Development 24
3. IMPLEMENTATION 25
3.1. Preparation of the Artifact 25

3.2. Packaging/Shipping/Handling 25
3.3. Materials Handling and Storage 26
4. ANALYSIS 27
4.1. Determination of Assigned Reference Values and its Associated Uncertainty 27
4.2. Performance Evaluation of Participants 27
4.3. Outlier Detection Techniques 28
4.4. Assessing the Stability of the Artifact 29
4.5. Assessing Homogeneity of Artifact 29
5. REPORTING 31
5.1. Schedules 31
5.2. Preliminary Reports 31
5.3. Final Reports 31
APPENDIX A - FORMS 32
Form 1: PT/ILC Planning Checklist 33
Form 2: PT/ILC Reporting Checklist 36
Form 3: PT/ILC Training & Qualifications 38
Form 4: PT/ILC Feedback and Complaints 41
Form 5: WMD Quality System Management Review 42
Form 6: WMD Internal Audits for PT/ILC Activities 44
Form 7: NIST WMD Nonconformance/Corrective Action/Preventive Actions (NCAP) 47
Form 8: Schedule & Shipping 49
APPENDIX B – PROCEDURES & POLICIES 50
Procedure 1: PT/ILC Software Validation Procedure 51
Procedure 2: Selection of Delegates 52
Policy: NISTIR 7082 "Proficiency Test Policy and Plan (for State Weights & Measures Laboratories)" (on-line at http://www.nist.gov/labmetrology) 53

ABSTRACT

This document has been prepared by Jeff C. Gust (Quametec Corp., under contract) in collaboration with NIST Weights and Measures Division (WMD) to enable State Weights and Measures Laboratories to comply with criteria for proficiency testing as noted in NIST Handbook 143 and as needed for accreditation programs. This document is intended to provide the basic quality system for Proficiency Testing and Interlaboratory Comparisons developed by NIST Weights and Measures Division.

Acknowledgement

The following individuals participated in the development and review of this document:

Richard Cote, New Hampshire Department of Agriculture
Doug Faison, NIST/National Voluntary Laboratory Accreditation Program
Ken Fraley, Oklahoma Bureau of Standards
Elizabeth Gentry, Oklahoma Bureau of Standards
Tom Hale, Pennsylvania General Services Administration
Georgia L. Harris, NIST/Weights and Measures Division
Carol Hockert, Minnesota Department of Commerce, Weights and Measures Division
Van Hyder, NC Department of Agriculture & Consumer Services, Standards Laboratory
G. Diane Lee, NIST/Weights and Measures Division
Val Miller, NIST/Weights and Measures Division
Steve Schultz, Nevada Department of Agriculture, Bureau of Weights and Measures

INTRODUCTION

Scope

This document has been developed for the NIST Technology Services, Weights and Measures Division (WMD) in order to establish and implement a quality system for the planning, implementation, analysis, and reporting of Proficiency Tests (PT) and Interlaboratory Comparisons (ILC) conducted within the WMD Measurement Assurance Program (MAP). This document contains the NIST QMD Quality Manual for Proficiency Testing and Interlaboratory Comparisons. This document provides the quality system to ensure that all Proficiency Testing and Interlaboratory Comparison activities within WMD are compliant with ILAC-G13:2000, *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes and* ISO/IEC Guide 43-1:1997, *Proficiency Testing by Interlaboratory Comparisons – Part 1, Development and Operation of Proficiency Testing Schemes*. This document specifies requirements to ensure that NIST WMD and associated delegates are technically competent to provide specific types of proficiency testing schemes as required by NISTIR 7082, Proficiency Test Policy and Plan (for State Weights and Measures Laboratories), 2004.

Document Retention

This document has no expiration date and remains in effect until revised, replaced, or retired.

References

Compilation of Federal Ethics Laws (approved through May 27, 2003) – Prepared by the United States Office of Government Ethics. [Web page], http://www.usoge.gov/pages/laws_regs_fedreg_stats/comp_fed_ethics_laws.pdf.

Gust, J. C. and Harris, Georgia L. Proficiency Test Policy and Plan (for State Weights and Measures Laboratories). National Institute of Standards and Technology, (U.S.) NISTIR 7082, 2004 January [Web page] http://www.nist.gov/labmetrology.

Harris, Georgia. L. State Weights and Measures Laboratories Program Handbook, 4th Edition. National Institute of Standards and Technology (U.S.) Handbook 143; 2003, March. [Web page] http://www.nist.gov/labmetrology.

Harris, Georgia. L. State Weights and Measures Laboratories: State Standards Program Description and Directory. National Institute of Standards and Technology (U.S.) NIST SP 791, 2000 Edition; 2000 August. [Web page], http://ts.nist.gov/ts/htdocs/230/235/labdirectory/sp791.htm [last updated 10/1/02].

ILAC-G13:2000, Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes. International Laboratory Accreditation Cooperation, 2000.

ISO/IEC Guide 43-1:1997, Proficiency Testing by Interlaboratory Comparisons – Part 1: Development and Operation of Proficiency Testing Schemes. International Organization for Standardization, 1997.

ISO/IEC 17025:1999, General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, 1999.

National Conference of Standards Laboratories (NCSL) Recommended Practice, RP-15, Guide to Interlaboratory Comparisons, 1999 March.

NIST/SEMATECH e-Handbook of Statistical Methods, [Web page], http://www.itl.nist.gov/div898/handbook/, National Institute of Standards and Technology (U.S.) Handbook 151, 2002 November.

Definitions

Analyst – Assigned person who is responsible for handling all data related activities for the Proficiency Test or Interlaboratory Comparison (PT/ILC). (As used in this publication "PT/ILC" is used generically to mean either a Proficiency Test or an Interlaboratory Comparison; the specific objectives and context will determine the application and use of PT/ILC results.)

Coordinator – A party who is responsible for implementation of the PT/ILC.

Delegate – Any party outside of NIST, Technology Services, WMD who volunteers or accepts a task related to the PT/ILC from the Technical Manager who works with the WMD to accomplish its proficiency testing objectives, whether volunteer or contractor. Delegates may include: analysts, coordinators, pivot laboratories, reference laboratories, and regional administrators.

Interlaboratory Comparison – a generic term for the circulation of an artifact, standard, or set of standards for the purpose of evaluating measurement results.

NIST POC – Assigned point of contact within NIST WMD for the PT/ILC.

Participant – Any organization meeting RMAP (see definition) requirements for participation in a PT/ILC.

Pivot Laboratory – Laboratory organization that determines stability value for the artifact.

Provider – NIST Weights and Measures Division is considered the "provider."

Proficiency Test – A specific interlaboratory comparison that may be used by a laboratory or Recognition and/or Accreditation bodies as evidence of staff competence.

Reference Laboratory – Laboratory organization that determines the reference value for the artifact.

RMAP – Regional Measurement Assurance Program.

Regional Administrator – Regional coordinator who assists in tracking the status of all PT/ILCs within the region.

Technical Manager – The Technical Manager is the Group Leader for the WMD Laboratory Metrology Group.

1. ADMINISTRATION

1.1. Quality System & Policy

1.1.1. This document establishes, implements and maintains the quality system for proficiency testing and interlaboratory comparison activities of NIST WMD for the scope of Measurements that are defined in section 1 of NISTIR 7082, Proficiency Test Policy and Plan (for State Weights and Measures Laboratories).

1.1.2. This document defines and documents the WMD's policy, objectives and commitment to ensuring and maintaining quality of all aspects of proficiency testing. Artifact quality, characterization, and assignment of property values are described in *PLANNING*. Evaluation of each laboratory's performance and statistical treatment of test results are described in *ANALYSIS*. Distribution of artifacts, storage and transport procedures are described in *IMPLEMENTATION*. Reporting procedures are described in *REPORTING*.

1.1.3. Quality Policy: NIST WMD pledges to provide proficiency testing services using metrologically sound practices and the highest levels of service quality as documented in this quality system. All staff and delegates associated with proficiency testing services pledge to adhere to the policies and procedures documented in this quality system, performed in accordance with ILAC G13:2000, ISO/IEC Guide 43-1, and relevant sections of ISO/IEC 17025:1999.

1.1.4. The locations of the applicable sections of ILAC G13 are as follows:

ILAC G13 Requirement, Section 2.1.3, section letter		Quality Manual Section
a	Aims	Introduction
a	Scope	NISTIR 7082
a	Statistical Design	Analysis
a	Format	Reporting
b	Operational Procedures	Implementation
c	Preparation and Issuing of Reports	Reporting
d	Policies on Confidential and Ethical Procedures	Administration
e	Computing and Information Systems	Administration
f	Collaboration and Sub-contracting	Administration
g	Fees for Participation	Administration
h	Scope of Availability of Proficiency Testing Programs	Regional MAP Programs
i	General Policies on Participation	Administration
j	Use of Scheme Results	Administration
k	Procedures for Handling Complaints	Administration

1.1.5. Throughout this document, the responsibilities for all activities are defined in each applicable section.

1.2. Organization and Management

1.2.1. The organization providing proficiency tests within the scope of this document is NIST, Technology Services, Weights and Measures Division (Division 260.)

1.2.2. The Technical Manager and Quality Manger (as assigned by the WMD Laboratory Metrology Group Leader) task other personnel within the WMD Metrology Group and Delegates to complete all aspects of PT/ILC within the scope of this program.

1.2.3. In order to ensure that all management and personnel are free from any commercial, financial, internal, or external pressures that may adversely affect the quality of PT/ILC activities, all Federal Employees are subject to abide by the Federal ethics laws as cited in the "Compilation of Federal Ethics Laws". Additionally, all appointed Delegates must comply with all elements contained in *POLICY FOR PARTICIPATION* which is

intended to ensure freedom from external pressures. These policies also ensure that all personnel involved in PT/ILC activity avoid involvement in activities that might diminish the confidence in the competence, impartiality, judgment, or operational integrity of NIST WMD.

1.2.4. It is the policy of NIST WMD that all PT/ILC activities are completely open, with no coded or confidential information. All participants must agree to these conditions before being qualified to participate in PT/ILC activities. This document may be used to develop PT/ILC activities for the NIST National Voluntary Laboratory Accreditation Program (NVLAP) at their request. For this special case, access to information which results from PT/ILC activities is restricted to a minimum number of people and the reported information may be coded to ensure the confidentiality of the participants where NVLAP determines that it is necessary.

1.2.5. WMD may occasionally coordinate PT/ILC activities for NVLAP or other accreditation bodies when it is in the interest of WMD program objectives. In these cases, WMD will follow the confidentiality policies of the accreditation bodies if requested.

1.2.6. NIST WMD has developed organization charts to define its Organization and Management structure, its place within NIST, and the relations between management, technical operations, support services, and delegates. The organization charts also demonstrate the responsibility, authority, and interrelationships of all personnel who manage, perform or verify work in PT/ILC activities.

1.3. Roles and Responsibilities

1.3.1. The Technical Manager has overall technical responsibility for each PT/ILC activity. The Technical Manager or Designee from NIST WMD reviews and provides final approval on all PT data, analysis, and reports. Final approval of PT data, analysis, and reports may not be assigned to personnel outside of NIST WMD.

1.3.2. The Technical Manager must have experience with PT/ILC activities that are conducted within the scope of NISTIR 7082. The Technical Manager must have the educational and technical background required to meet a position for a Physical Scientist ZP III within NIST WMD, Laboratory Metrology Group. The requisite background includes extensive experience in calibration of standards of mass, length, and

volume; experience in developing calibration procedures and methods; participation in, or coordination of, round robins or other interlaboratory experiments and comparisons; and experience in quality system operations and audits.

1.3.3. The Quality Manager has responsibility for all quality related aspects of this program such as the maintenance of records, Internal Audits, and ensuring adherence to policies and procedures.

1.3.4. The Quality Manager must have experience and training as a lead auditor in a metrology-related field (e.g., ISO 9000, ISO/IEC 17025).

1.3.5. The Technical and Quality Managers, and their deputies shall be assigned by the WMD Laboratory Metrology Group Leader via email or memo, which are retained as a correspondence quality record.

1.4. Collaboration and Subcontracting

1.4.1. The Technical Manager may designate activities from the *PLANNING, ANALYSIS, IMPLEMENTATION,* and *REPORTING* sections of this document to collaborators who will hereby be known as Delegates.

1.4.2. Delegates are selected based upon an assessment of technical qualifications as determined by the Technical Manager or Designee. All Delegates are evaluated using procedures and records described in the Training section of the *ADMINISTRATION* section.

1.4.3. Laboratories that are selected for establishment of the reference value or performance of pivot measurements must be either accredited in the measurement parameter of concern by an accreditation body that is a signatory to the ILAC, MRA (International Laboratory Accreditation Cooperation, Mutual Recognition Arrangement http://www.ilac.org), or recognized for compliance to NIST Handbook 143 by NIST for the measurement parameter of the PT/ILC, and be able to provide a suitable level of measurement uncertainty for the proposed PT/ILC. Records of competency for any laboratory used for measurement activities are maintained in the WMD files and databases. Laboratory qualification may include one or more measurement areas and/or PT/ILCs. Laboratory recognition/accreditation status and records must be evaluated for accuracy and updated as needed, prior to each assigned PT/ILC.

1.4.4. Subcontracting, if coordinated, will be performed with organizations that are accredited to perform PT/ILCs and/or comply with this quality system.

1.5. Fees

1.5.1. NIST does not charge fees for participation in any PT/ILC activities. Commercial Laboratories that participate in PT/ILC activities are to pay costs of shipping to and from their laboratory. This requirement may be waived if they are serving as a delegate for the PT/ILC.

NOTE: Fees charged for attendance at the RMAP meetings are for coordination and costs associated with the meeting functions and not those of operating the proficiency testing programs. Attendance at the meetings, which is required to obtain reports and participation in the discussions, will usually require payment of fees associated with the cost of the meetings (distinct from the cost of the PT/ILC activity).

1.6. Policy for Participation

1.6.1. Any laboratory organization (Participant) that would like to participate in a PT/ILC activity within the scope of this document must agree to operate in accordance with the policies and conditions for participation as described in this quality system as follows:

1.6.1.1. The Participant will follow instructions for each PT and use designated procedures when instructed.

1.6.1.2. The participant must acknowledge that all NIST WMD PT/ILCs are considered OPEN and that anonymity is not implied or guaranteed.

1.6.1.3. The Participant will not use any PT/ILC report for any purpose other than internal measurement assurance or accreditation/recognition activities (no sales, marketing, or advertising of the results of any participating laboratory).

1.6.1.4. The Participant will not falsify any results submitted to NIST WMD.

1.6.1.5. The Participant agrees to keep details regarding the PT/ILC in confidence. It is inappropriate to share information (specifically measurement results) regarding the artifacts provided in the proficiency test final report or to seek to obtain measurement information for

artifacts prior to participation in the proficiency test (i.e., participants will share data only with the coordinator, analyst or NIST staff).

Exception: Draft E_n values or notice of significant error/bias may be communicated to individual laboratories, with follow-up monitoring by the ILC coordinator or by NIST to enable immediate investigation, corrective action, and retesting (if needed).

1.6.1.6. The participating organization will regularly attend RMAP meetings and participate in PT/ILC discussions.

1.6.1.7. Participants and participating organizations will be technically qualified for the measurement parameter of interest.

1.6.2. NIST WMD reserves the right to refuse participation to any organization, even if they are technically qualified, if the participant or participating organization has violated quality policies, procedures for care and handling of artifacts, repeated technical delays, or other technical issues that could potentially adversely affect the results for the other participants. Prior to WMD issuing a notice of refusal to a laboratory, due efforts will be made to notify participants in this category, provide guidance, and ensure that the laboratory has an opportunity for corrective action.

1.7. Document Control

1.7.1. Document control is maintained by NIST WMD, with approved documents for this quality system published and available for unlimited distribution on the World Wide Web at http://www.nist.gov/labmetrology (select Proficiency Testing Program). Any paper copies of quality documents used for any purpose must match the revision and date of issue as the associated document posted at the website. WMD will make general announcements to all staff and delegates when updates have been made. The approved, controlled copies of publications will be electronic and retained on the website. Copies will be retained for local use and back-up on NIST or WMD networks.

1.7.2. All documentation related to the scope of this quality manual is reviewed and approved for use by the Technical Manager prior to issue. The master list of approved documents is located at http://www.nist.gov/labmetrology.

1.7.3. All documentation will be technically reviewed for content and policy and assigned a publication number as per the requirements of NIST's editorial review and approval process, the Washington Editorial Review Board (WERB) in Gaithersburg, MD

1.7.4. Documentation related to this quality system is reviewed during Internal Audits and through regular use by all participants to ensure continuing suitability. Documents are also reviewed by personnel during each use. Any issues of suitability are communicated to the Quality Manager in writing.

1.7.5. During the document revision process, any document that has been revised will be removed from the website and replaced with the most current revision. Historical documents may be maintained on the website if they have been suitably marked as "OBSOLETE, REFERENCE ONLY" so that the historical nature is obvious if used.

1.7.6. Any invalid or obsolete documents maintained by NIST WMD for historical purposes are marked as "OBSOLETE, REFERENCE ONLY."

1.7.7. Any revisions to documents will be reviewed and approved by the Technical Manager. Minor changes to documentation will be described in the revision history for the document. Major changes to the documents will be identified by the word processing software "track changes" function and maintained by the Technical Manager. Hand-written changes will not be used.

1.8. Request, Tender or Contract Review

1.8.1. NIST WMD program is not a commercial PT/ILC organization. All PT/ILC activities occur as a result of WMD direction and/or RMAP participation in the development of PT/ILC. The contract review function is completed as a result of all members reaching consensus in the development of the PT/ILC as documented on the PT/ILC Planning Checklist (Form 1) for the RMAP's form. All participants must agree to abide by all elements of *POLICY FOR PARTICIPATION*. Any individual request for a new member or a member of another RMAP to participate in a PT/ILC that has already been developed and is operating must be submitted to the NIST WMD office for review, documentation and approval by the Technical Manager. Records of the PT/ILC Planning Checklist, individual requests to participate, and any associated changes are reviewed, approved, and maintained by the NIST WMD office.

1.8.2. PT/ILCs are communicated to participants outside of the RMAPs, usually via email or the NIST WMD website. The NIST WMD website provides an informational overview for each PT/ILC and whether or not it has openings for individual requests to participate. Special requirements for participation are noted/posted where applicable.

1.8.3. Any changes in the scheme design or operation of a PT/ILC are communicated to all participants in writing. Changes are maintained with WMD records for each PT/ILC.

1.8.4. When PT/ILC functions are coordinated with or on behalf of NVLAP, specific changes to the operation of a PT/ILC that are in conflict with this quality manual must be documented and retained on file.

1.9. Procurement of Services and Supplies

1.9.1. NIST WMD uses the Federal Acquisition Requirement (FAR) policies and procedures for procurement of all services and supplies. The Technical Manager or Designee develops and documents technical specifications, tolerances, and other requirements for all procured services and supplies, which are used in selecting suppliers. Upon receipt of items that affect the quality of PT/ILC services provided, the items are inspected for conformance to the documented technical requirements. For certain artifacts the reference laboratory may be required to perform the final inspection in order to ensure that the artifact is suitable for use in the PT/ILC. Final reports and analyses are reviewed and documented by the Technical Manager or Designee. Records of procurement and inspection are maintained by NIST WMD.

1.9.2. When items are used for PT/ILC activities that do not belong to WMD, suitable evaluation and assessment must be conducted and documented to ensure that artifacts are of sufficient quality to meet the stated objectives of the PT/ILC.

1.10. Client Feedback

1.10.1. Feedback from participants is sought during each RMAP meeting, in order to improve PT/ILCs that are developed within the scope of this document. The PT/ILC Feedback and Complaints Form (Form 4) and the WMD Quality System Management Review Form (Form 5) will be used to

ensure the uniform collection and consolidation of feedback from all RMAPs.

1.10.2. Complaints and feedback may be recorded by an ILC Coordinator, a delegate of the ILC, or the WMD office staff. Records of such feedback or complaints and their associated investigation and corrective actions are maintained through completion of the PT/ILC Feedback and Complaint Form (Form 4) or the WMD Nonconformance/Corrective Action/Preventive Action (NCAP) Form (Form 7). Evaluation of criteria for conformance and non-conformance is performed by the Technical Manager in accordance with Section 1.11.

1.11. Control of Nonconforming Activities and Corrective Action

1.11.1. In the event that any aspect of activities within the scope of this document is identified as nonconformity to the procedures or the stated requirements, it is the responsibility of the Technical Manager to investigate and determine appropriate corrective action. The corrective action process is applied to all identified nonconformities and shall be appropriate to the magnitude of the problem encountered.

1.11.2. All aspects of the nonconformance are recorded on the WMD Form 7 (NCAP). It is the responsibility of the Technical Manager to:

1.11.2.1. investigate and determine root cause of nonconformance;
1.11.2.2. evaluate the significance of the nonconformance;
1.11.2.3. identify potential corrective actions and select the action most likely to eliminate the problem and prevent it from reoccurring;
1.11.2.4. ensure work is halted if necessary;
1.11.2.5. assign a timescale for completion of corrective action;
1.11.2.6. obtain funding if needed; and
1.11.2.7. initiate corrective actions as required.

1.11.3. If necessary, participants are notified in writing and nonconforming materials or reports are recalled. Upon completion of corrective actions, the Technical Manager may authorize the resumption of the process/scheme.

1.11.4. Any corrective actions are monitored by the Quality Manager during the Internal Audits to ensure that the corrective action was effective.

1.12. Preventive Action

1.12.1. All operational procedures are reviewed during the Internal Audit and upon each use by all staff and delegates in order to identify opportunities for improvement. Any preventive actions and their associated action plans are identified and recorded on WMD NCAP Form (Form 7). Results of preventive actions are monitored and reviewed during Internal Audits and Management Reviews in order to understand the effectiveness of the preventive action.

1.13. Records

1.13.1. The following types of records are identified and indexed as quality records for NIST WMD PT/ILC activities. They are collected at time of generation, and stored by marked section in file cabinets or in electronic version on computer. The retention times for all documents are at least ten years after the completion of the test or retirement (or loss) of the artifact or proficiency test. After ten years, the Quality Manager may dispose of records at his/her discretion.

1.13.1.1. Master Document List
1.13.1.2. Previous editions of controlled documents and obsolete documents
1.13.1.3. Client Feedback
1.13.1.4. Artifact History Records and Inventory List
1.13.1.5. Customer Complaint/Feedback Log and Information
1.13.1.6. Nonconformities
1.13.1.7. Corrective Actions
1.13.1.8. Preventive Actions
1.13.1.9. Proficiency Test/Interlaboratory Comparison Records
1.13.1.10. Proficiency Test/Interlaboratory Comparison Reports
1.13.1.11. Internal and External Audits
1.13.1.12. Management Reviews
1.13.1.13. Training Schedule and Training Records (i.e., Form 3)
1.13.1.14. Assignment of Deputy Technical and Quality Manager
1.13.1.15. Software Validation Records
1.13.1.16. Correspondence Records

1.13.2. The storage facilities for records are at the NIST WMD office. Back-up copies of electronic records are maintained on the NIST network. NIST's Information Technology (IT) back up services and security features are administered following policies and procedures set by the NIST Office of Chief Information Officer.

1.13.3. The records are stored in the NIST WMD offices so that only employees have access to the hard copy records. Electronic copies of records are stored on the hard drives and network of NIST WMD computers and are appropriately password protected.

1.13.4. To prevent unauthorized amendment of data, Electronic Data is protected via password protection of operational features for each person's PC, and backed up to CD ROM media, to prevent unauthorized amendment of data.

1.13.5. Technical records contain information as prescribed in *REPORTING* and are maintained as a quality record.

1.14. Internal & External Audits

1.14.1. An Internal Audit of the quality system related to this document is completed annually, as scheduled by the Quality Manager. The audit may be performed by sections so that the entire quality system is reviewed annually.

1.14.2. The Quality Manager is primarily responsible for the planning and conduct of the Internal Audit. The schedule for the Internal Audit will be determined at the time of the Management Review meeting. The Quality Manager may designate individuals to perform parts of the Internal Audit and will ensure the training and qualifications of such individuals. Internal Audit Results are collected and summarized on the WMD Internal Audit Form (Form 6).

1.14.3. The Internal Audit shall review all elements and activities associated within the scope of this document. During the Internal Audit, all documents and program elements are reviewed for continuing effectiveness and potential for improvement. Any nonconformities identified throughout the previous year are reviewed for closure and effectiveness. Any nonconformities identified during the Internal Audit will be addressed by following the policy in ADMINISTRATION - Control of Nonconforming Activities and Corrective Action.

1.14.4. Any External Audits that are authorized and conducted will follow appropriate or applicable standards as determined by the Technical and/or Quality Manager. Such records will be retained with other auditing records and discussed during Management Reviews.

1.15. Management Review

1.15.1. RMAP PT/ILC Quality System Review

1.15.1.1. NIST WMD conducts management reviews of the quality system and PT/ILC activities as applicable within each RMAP during the annually scheduled meeting of the RMAP. Any suggestions for changes or improvements are summarized in report form (Forms 4 and 5) for discussion at the annual Management Review meeting.

1.15.2. NIST WMD PT/ILC Quality System Review

1.15.2.1. NIST WMD conducts a Management Review meeting of the quality management system annually, as scheduled by the Technical Manager. The Management Review meeting discusses:

1.15.2.1.1. Suitability and effectiveness of the Quality System
1.15.2.1.2. The Quality and applicability of PT/ILC Activities
1.15.2.1.3. Reports from RMAP meetings (Forms 4 and 5)
1.15.2.1.4. Reports from Internal Audits (Form 6)
1.15.2.1.5. Reports of External Audits (e.g., NVLAP, A2LA, L.A.B., other requested body)
1.15.2.1.6. Client feedback/complaints
1.15.2.1.7. Resources (facilities, standards, and equipment)
1.15.2.1.8. Outstanding items from previous Management Review
1.15.2.1.9. Staff Training
1.15.2.1.10. Other relevant reports

1.15.2.2. The minutes of the Management Review meeting are recorded and any actions or improvement suggestions are assigned to appropriate personnel with an estimated completion date to ensure completion within an appropriate and agreed upon timescale.

1.16. Management Staffing and Training

1.16.1. Training

1.16.1.1. The Technical Manager has responsibility for the management of all PT/ILC activities associated with NIST WMD. The Technical Manager is responsible for ensuring that all personnel who have any responsibilities associated with any PT/ILC activities are sufficiently trained.

1.16.1.2. The Coordinator, Delegate, and Analyst positions as assigned for PT/ILC activities must have adequate training to ensure that they have the technical capability to complete the duties as assigned. It is the responsibility of the Technical Manager to annually develop a training plan and ensure that essential training is conducted to ensure the competency of all personnel involved in the PT/ILC activities.

1.16.1.3. Participant training and qualifications shall be documented using the PT/ILC Training and Qualifications form (Form 3) to verify adequate training and ensure that they possess the technical capability to participate within specific PT/ILC parameters.

1.16.1.4. Records of training for all personnel involved with PT/ILC management activities are maintained using Form 3 and database developed and maintained by NIST WMD for training records.

1.16.2. Staffing

1.16.2.1. The Technical Manager is responsible for ensuring sufficient staffing for each PT/ILC and that all personnel involved in PT/ILC are qualified. The Technical Manager reviews the training records of all personnel involved to ensure the effective management of all PT/ILC activities. Records of training for all personnel involved with PT/ILC management activities are maintained using a database developed and maintained by NIST WMD for training records.

1.17. Collusion and Falsification of Results

1.17.1. Each PT/ILC activity is designed to ensure, as is practicable, that the possibility for collusion and falsification of results is minimized. It is the responsibility of the PT/ILC Coordinator to monitor the activities of the PT/ILC and to ensure that there is no communication of the assigned values to or among participants until the results of the PT/ILC activity have been collated in a draft report. In addition to the PT/ILC coordinators monitoring activities to this end, each participant in PT/ILC activities within the scope of this document is required to comply with all elements of *POLICY FOR PARTICIPATION.*

1.18. Data Processing Equipment

1.18.1. NIST WMD utilizes personal computers, laptop computers, and scientific calculators for data entry and statistical analysis of PT/ILC

activities, all of which are adequate for the assigned task. Deficiencies noted with data processing equipment are brought to the attention of the Technical Manager, and are addressed during Internal Audits and Management Reviews as appropriate.

1.18.2. The IT activities of NIST or the IT Department of Delegate organizations are responsible for the effective operation of laptop and personal computers. Calculators are a disposable item and are replaced by the user if any abnormal operation is detected. Use of appropriate significant digits is considered in data evaluation and addressed as needed during ongoing training of staff/delegates.

1.18.3. Commercial Software programs such as Microsoft Excel do not require further validation. Sub-programs such as worksheets for the analysis, evaluation, and reporting of results for activities within the Scope of this document require validation before use as per the PT/ILC Software Validation Procedure (Procedure 1).

1.18.4. Records of objective evidence for the validation and revision date of the software are maintained at NIST WMD by the Quality Manager. The distribution of any such software is accomplished through the NIST WMD website, by email, or by sharing of files through other electronic means. The software on the NIST WMD website is the master copy of the software and it is backed up routinely by NIST IT procedures.

2. PLANNING

The general PT/ILC requirements are plans developed in accordance with NISTIR 7082, during Management Review and RMAP meetings.

A PT/ILC begins with the planning activities performed by an advisory group. This group may be assembled by the Technical Manager for national level PT/ILC activities or may consist of an RMAP group (or subgroup). The advisory group plans the PT/ILC activity by completing the PT/ILC Planning Checklist Form (Form 1).

2.1. Technical Protocol Development

2.1.1. The Technical Manager or Delegate develops the Technical Protocol for the PT/ILC based upon the information obtained in the associated PT/ILC Planning Checklist form (Form 1). The Technical Protocol shall contain the following information, as relevant:

- Environmental Conditions for Realizing the Measurement Results for the Artifact;
- Environmental Conditions for Storage and Transport for the Artifact;
- Preparatory Information for the Artifact(s);
- Packaging and Shipping Information of the Artifact and tracking requirements;
- Communication to the participants to treat the artifact in the same manner as routine measurements for the method prescribed or other specified instructions on handling;
- Instructions of the measurement method to be used in the PT/ILC;
- Reporting Requirements for Participating Laboratories:
  - Units of measurement;
  - Number of significant digits;
  - Date of measurement;
  - Reporting reference/basis of measurement (e.g., environmental conditions, reference temperature);
  - Measurement value and its associated expanded uncertainty (the reported measurement uncertainty must be the actual calculated uncertainty, not just a transfer ratio);
  - Uncertainty analysis (components included or not included); and
  - The laboratory report on the method used if different than prescribed in the Technical Protocol; and
- Directions on how to return or submit the data.

3. IMPLEMENTATION

3.1. Preparation of the Artifact

3.1.1. The artifact(s) is/are selected (as described in Section 1.9) for the PT/ILC based upon requirements documented in the PT/ILC Planning Checklist and *Procurement of Services and Supplies*. The artifact(s) may be loaned from organizations such as NIST WMD or other laboratories as long as appropriate planning is taken to ensure that the reference value has not been previously known by participating laboratories.

3.1.2. The Reference Laboratory (where used) and Pivot Laboratory (where used) are qualified based upon information obtained in the PT/ILC Planning Checklist. Records of qualification for the Reference Laboratory and Pivot Laboratory are created per *Collaboration and Subcontracting* (Section 1.4).

3.1.3. The Technical Manager will develop any additional processes to determine the stability of the artifact as necessary. The artifact(s) is/are then sent to the Reference Laboratory for the establishment of its reference value(s) or to the Coordinating Laboratory where the reference value is selected using alternative methods.

3.1.4. The Technical Manager or delegate reviews qualifications for potential participating laboratories via training databases maintained by NIST WMD and/or completed on the PT/ILC Planning Checklist (Form 1).

3.1.5. The PT/ILC Coordinator then develops a schedule for the PT/ILC activity based upon the final list of participating laboratories and the number of pivot measurements (when used). The schedule may be communicated and tracked in the most convenient and practical way for the PT/ILC Coordinator.

3.1.6. The PT/ILC is initiated according to the schedule.

3.2. Packaging/Shipping/Handling

3.2.1. The PT/ILC Coordinator is responsible for shipping the artifact(s) using appropriate packaging methods for the particular artifact(s), along with any additional considerations that were identified in the PT/ILC planning checklist Planning Checklist (Form 1).

3.2.2. The PT/ILC Coordinator and each Participating Laboratory is responsible for ensuring that:

- Standards are appropriately packaged;
- Shipping containers are appropriately labeled; PT/ILC instructions are securely attached to the product packaging of individual units and designed to remain legible and intact for the period of use in the PT/ILC;
- The PT/ILC instructions and forms should generally be included in the shipping container. A minimum of a packing list and the WMD shipping address will be included with all PT/ILC artifacts.
- Standards are shipped by an appropriate commercial carrier or by other methods as identified in the ILC Schedule (Form 8) & shipping instructions; and
- Standards are protected from adverse environmental conditions (i.e., protection of heat, cold, x-rays) as appropriate.
- Any damage or loss sustained by any standards, artifacts, or shipping containers, is immediately reported to NIST/WMD.

3.3. Materials Handling and Storage

3.3.1. The PT/ILC Coordinator is responsible for short-term storage of artifacts during gaps in the schedule, and the Technical Manager is responsible for long-term storage of artifacts. Whether artifacts are in long term or short term storage, the responsible party is accountable for identification, preservation, and segregation of all artifacts from incompatible environments or materials such as high humidity, uncontrolled temperatures, or chemicals and other items so that the artifacts do not deteriorate during storage.

3.3.2. The Technical Manager maintains the inventory list of artifacts in long-term storage and is responsible for developing schedules of periodic inspection for possible deterioration as appropriate for the artifacts.

4. ANALYSIS

4.1. Determination of Assigned Reference Values and its Associated Uncertainty

4.1.1. The method for determining the assigned value is documented on the PT/ILC Planning Checklist (Form 1) prior to beginning the PT/ILC activity. The method selected must be based upon sound metrological and statistical principles. Documents listed in the *REFERENCES* section of this manual may be utilized, but this list is not necessarily an all-inclusive list. Any determination of the reference value must include consideration of stability of the artifact as each participant performs measurements. The Expanded Uncertainty of the PT/ILC will be the combination of the reference value uncertainty and the uncertainty associated with stability. Some examples used for determining reference values may be:

- The Reference Laboratory (such as NIST or an accredited laboratory) measured value (stability may be determined by Pivot Laboratory measurements);
- The mean of the Reference Laboratory measured values from the beginning and end of the PT/ILC;
- The median of the results from accredited laboratories;
- The median of one result from each participating laboratory; or
- The adjusted median of the participating laboratories

Documented procedures for selecting reference values will be used.

4.2. Performance Evaluation of Participants

4.2.1. The method of evaluating performance for the participants and acceptable limits of performance is documented on the PT/ILC Planning Checklist (Form 1) prior to beginning the PT/ILC activity. The method selected must be based upon sound metrological and statistical principles. Documents used in the *REFERENCES* section of this document manual may be utilized, but this list is not necessarily all-inclusive. Some examples of determining performance of the Participant may include:

- Determination of Normalized Error value, E_n; ($E_n > 1$ is considered a failure)
  - While an E_n value > 1 is considered a failure; the analyst may recommend additional follow up for an E_n value between 0.5 and 1.

- Precision Tests (The reported uncertainty must be less than specified limits for some applications);
- Z score value;
- Participant measurement is within the expanded uncertainty of the PT/ILC;
- Participant value shows a bias even though their reported uncertainty is large enough to pass the E_n analysis; and
- Participant measurement result(s) and associated expanded uncertainty is within the expanded uncertainty of the PT/ILC.
- Expanded uncertainty (variations due to laboratory capabilities, bias, uniformity of methodology employed, etc.)

4.2.2. When assessing the technical competency of a participating laboratory, appropriate technical specialists and statisticians (or technical approaches and statistical tools) are used as deemed appropriate by the Technical Manager. Each PT/ILC report will contain both individual and summary analyses.

4.2.3. Other Performance Analysis issues to evaluate may be:

- Overall performance against prior expectations, taking measurement uncertainties into account;
- Variation within and between laboratories, between RMAP results, and comparisons with any similar previous schemes or published precision data; and
- Variation between methods, procedures, or equipment used if applicable;
- Evaluation of a laboratory's timeliness in conducting and reporting their PT/ILC results; and
- Evaluating the laboratory's calibration report for compliance with ISO 17025 (Section 5.10) criteria.

4.3. Outlier Detection Techniques

4.3.1. The NIST/Sematech e-Handbook of Statistical Methods provides guidance on outlier detection or other special analysis techniques. Results of PT/ILC activities within the scope of this document are not discarded. Results that could be considered outliers, or results from laboratories performing measurements outside of their normal scope of recognition, may not be used for statistical summaries, but the information is included in draft and final reports. Any suspect data will be verified by the Technical Manager or Designee to ensure that the data entry and

transcriptions were performed correctly and that any data entry errors were identified, documented, and corrected. Data entry errors by participants are identified by feedback or reports issued by NIST WMD to the participant (or within the report), who will use their corrective action process for root cause analysis and response. The Technical Manager or Designee is responsible for follow-up of issued nonconformities.

4.4. Assessing the Stability of the Artifact

4.4.1. The method for determining artifact stability is documented on the PT/ILC Planning Checklist (Form 1) prior to beginning the PT/ILC activity. The method selected must be based upon sound metrological and statistical principles. Documents described in the *REFERENCES* section of this document manual may be used, but this list is not necessarily all-inclusive. Limits of acceptable stability for the artifact are also determined and recorded on Form 1 prior to beginning the activity. It is the responsibility of the Technical Manager to communicate the limits of artifact stability to the Pivot Laboratory so that they can evaluate the artifact stability during the PT/ILC and alert the Technical Manager if stability limits have been exceeded. If established limits have been exceeded, it is the responsibility of the Technical Manager to determine how to proceed.

4.4.2. Some examples of determining stability may include:

- The measured deviation between the opening and closing measurements performed by the Reference Laboratory;
- The standard deviation of the Pivot Laboratory measurements;
- The uncertainty of linear regression of the Pivot Laboratory measurements; and
- The standard deviation of participant measurements.

4.5. Assessing Homogeneity of Artifact

4.5.1. If homogeneity is determined to be applicable for the PT/ILC activity, the assessment of homogeneity is performed after the test material has been packaged in its final form and before distribution to participants unless, for example, stability studies indicate that it should be stored in bulk form. In some cases, an intermediate homogeneity check may be necessary, for example, before sealing into appropriate packaging.

4.5.2. The provider or its collaborators, where appropriate, shall use a statistically random selection of a representative number of samples from a batch of test material to assess the homogeneity of the material. This assessment procedure shall be documented and conducted in accordance with acceptable statistical designs, for example, analysis of variance on replicate results under repeatability conditions. In the case of measurement artifacts, preliminary stability checks shall be made and periodic checks of assigned property values should be carried out throughout the course of the scheme.

4.5.3. If appropriate, limits of acceptable homogeneity for the artifact are also determined and recorded on the PT/ILC Planning Checklist (Form 1) prior to beginning the activity.

4.5.4. It is the responsibility of the Technical Manager to communicate the limits of artifact homogeneity to the Pivot Laboratory so that they can evaluate the artifact homogeneity during the PT/ILC and alert the Technical Manager if the established limits have been exceeded. If established limits have been exceeded, it is the responsibility of the Technical Manager to determine how to proceed.

5. REPORTING

5.1. Schedules

5.1.1. The PT/ILC Coordinator develops and publishes Schedule & Shipping instructions based upon the information gathered in the PT/ILC Planning Checklist (Form 1). The schedule will be sent to all participants and may be posted at the NIST WMD website.

5.2. Preliminary Reports

5.2.1. Preliminary or Draft Reports may be issued to the participant(s) at the discretion of the Technical Manager. Since such reports may be requested before the closing measurement of the reference laboratory, the Analyst will need to perform evaluations based upon a given reference value or the opening measurement on the artifact by the Reference Laboratory and the evaluation of stability performed thus far in the PT/ILC activity. All participants are to review their preliminary report to ensure that all data on the report corresponds to the data that was submitted by the laboratory.

5.3. Final Reports

5.3.1. The content of the Final Report will vary depending on the purpose of a particular scheme, but each report shall be clear and comprehensive and include data on the distribution of results from all participants, together with an indication of the performance of individual participants. Final Reports are delivered prior to or at the RMAP meeting for discussion and comments.

5.3.2. Final Reports issued for PT/ILC activities within the scope of this document shall contain:

- Elements contained in the PT/ILC Reporting Checklist (Form 2);
- Any other suggestions, recommendations or general comments;
- Conclusions;
- Comments on the performance both of individual participants and on participation as a whole; and
- Possible sources of error (with reference to extreme results) and suggestions for improving performance.

APPENDIX A - FORMS

Number	Title
1	PT/ILC Planning Checklist
2	PT/ILC Reporting Checklist
3	PT/ILC Training & Qualifications
4	PT/ILC Feedback & Complaint
5	WMD Quality System Management Review
6	WMD Internal Audits
7	WMD Nonconformance, Corrective Action, Preventive Action (NCAP)
8	Schedule & Shipping (nonmandatory)

Form 1: PT/ILC Planning Checklist

Page 1 of 3

ILC Region & Planned Reporting Year:	
ILC Title:	
ILC Coordinator Name:	
ILC Coordinator Address:	
Names, position, and addresses of any other personnel involved in design and operation of ILC:	
Form Completed by:	

Nature and Purpose of ILC scheme:

Identification of the Measurand:	

Identification and description of Artifact(s):	
Description of nature of Artifact and why it was chosen:	
Artifact source (owner):	

Describe any stability issues with the artifact:

Identification of the test method used by the participants:

Identification of the type of equipment required by the participants:

Identification of the approximate uncertainty required by the participants:

Ranges of values expected from the participant measurements:

Form 1: PT/ILC Planning Checklist

Page 2 of 3

Any potential difficulties in preparation and maintenance of homogeneous materials or the provision of a stable reference value for the artifact:

Describe any homogeneity issues, as applicable:	

Describe any environmental issues with the artifact for storage, transport, or measurement:

Describe any special preparation issues for Artifact(s) as applicable:

Packaging/Handling issues, Special Containers needed?

The Criteria for participation in the ILC:

Reference Laboratory:	

Pivot Laboratory:	

Identification of Expected Participants: (identify laboratory and personnel to be involved in measurement):	
Are all laboratories and personnel qualified to participate (review NIST WMD training databases)	☐ yes ☐ no (if no, explain)

Design of test (i.e., petal, loop, etc.):	
Describe when artifact is checked and how it is distributed:	

Form 1: PT/ILC Planning Checklist

Page 3 of 3

Number of significant figures to which results are to be reported:	
Precision of test:	
Smallest differences expected between participants:	

Statistical Method for determining reference value of artifact:
Method of performance evaluation:
Acceptable limits of stability (from pivot measurements and overall):
Acceptable limits of homogeneity (if applicable):

Form 2: PT/ILC Reporting Checklist

Page 1 of 2

PT/ILC Identification:	
Coordinator:	
Date of Completion:	

Ensure that Final Report Contains the Following

Title Page or Introduction	
General Description and title of the ILC	
Names and affiliations of persons involved in design and conduct of PT/ILC	☐ Included
Date of issue of the report	☐ Included
Report number and clear identification of the PT/ILC	☐ Included
Dates (Time period of conduct of test from beginning to end)	☐ Included
RMAP group	☐ Included
Who	
Reference Laboratory	☐ Included
Pivot Laboratory	☐ Included
Participants (include address as appropriate)	☐ Included
What and Why	
Objectives	☐ Included
Parameter, Range, Uncertainty (e.g., mass, 1 kg, best calibration)	☐ Included
Clear description of the items or materials used, including, where appropriate, details of sample preparation and homogeneity testing	☐ Included
Details of the traceability and uncertainty of assigned values	☐ Included
How	
Summary of procedures used to design and implement the scheme (which may include reference to a scheme protocol)	☐ Included
Procedures Used	☐ Included
Laboratory Equipment Identification (e.g., which balance, which standards, for each lab)	☐ Included
Analysis	
Summary of procedure used to establish any assigned value	☐ Included
Summary of procedures used to statistically analyze the data	☐ Included
Software title and version used in data analysis	☐ Included

Form 2: PT/ILC Reporting Checklist

Page 2 of 2

Tables & Graphs	
Laboratory test results	☐ Included
Statistical data and summaries, including assigned values of Artifact(s), and range of acceptable results	☐ Included
Assigned values and summary statistics for test methods/procedures used by other participants (if different methods are used by different participants)	☐ Included ☐ N/A
Tables of data, precision tests, and evaluation data	☐ Included
Graphs of data, standard value/uncertainty charges, Youden plots, misc. graphs	☐ Included
Conclusions	
Comments on participants' performance by the provider and technical advisors	☐ Included
Summarization of Results	☐ Included
Recommended follow-up and corrective action (by analyst/by NIST)	☐ Included
Comments on any technical difficulties raised by participants	☐ Included ☐ N/A
Evaluation of the responses of participants performing poorly (if feedback is required)	☐ Included ☐ N/A
Advice, where appropriate, on the interpretation of the statistical analysis	☐ Included ☐ N/A

Return to NIST WMD For Archival – Copies and/or originals of:	
Instructions	☐ Included
Schedules	☐ Included
Datasheets	☐ Included
Formal Calibration Report (where requested)	☐ Included
Submitted Data	☐ Included
Analysis and electronic Documents/spreadsheets	☐ Included

Form 3: PT/ILC Training & Qualifications

(may be retained in electronic database)

Page 1 of 3

Name:	
Laboratory:	

Formal Education

SCHOOL ATTENDED	ATTENDED		COURSES COMPLETED	CERTIFICATE AWARDED	
	FROM	TO		YES	NO

Technical Seminars and Workshops Attended

DATE & PLACE ATTENDED	NAME OF SEMINAR/WORKSHOP ATTENDED	NUMBER OF HOURS OF INSTRUCTION	CERTIFICATE RECEIVED	
			YES	NO

Form 3: PT/ILC Training & Qualifications

(may be retained in electronic database)

Page 2 of 3

METROLOGY DISCIPLINE	TRAINING LEVEL	YEARS OF EXPERIENCE IN THIS DISCIPLINE	APPROVED FOR PT/ILC FUNCTIONS
Mass			
Echelon I			
Echelon II			
Echelon III			
Mass, Fluid Flow (Volume)			
Echelon I Gravimetric – Large Prover			
Echelon II Gravimetric – Small Volume (Glassware)			
Echelon II Volumetric – Large Volume Transfer			
Echelon II Volumetric – Small Volume Transfer			
Length, Dimensional, Linear			
Length Rulers			
Length Tape			
Temperature			
Echelon I			
Echelon II			
Echelon III			
Echelon IV			
Echelon V			
Misc.			
Hydrometers			
Tuning Forks			
Stop Watches and Timers			
Hygrometer/Relative Humidity			
Grain Moisture			

Reviewed and Approved By:	
Date of Review:	

See Training Level Codes on the next page.

Form 3: PT/ILC Training & Qualifications

(may be retained in electronic database)

Page 1 of 3

TRAINING LEVEL CODE LEGEND:

BLANK: No experience in the particular field

C: Introductory Experience such as on-the-job training (OJT), Computer Based Instruction, Informal Instruction, or Formal Instruction that is over ten years old.

B: Intermediate Experience such as formal instruction provided in house or by a NIST WMD approved metrology program.

A: Formal Instruction provided by a recognized subject matter expert such as original equipment manufacturer (OEM) training, or NIST seminars.

APPROVED FOR PT/ILC FUNCTIONS LEGEND:

The qualifications listed below are in ascending order of ranking (i.e., if the person is qualified as a coordinator, they are also qualified as a participant, but are not necessarily qualified as an analyst or for reports. A person qualified for reports is qualified for all PT/ILC activities for the parameter.

BLANK: Not approved for PT/ILC activities for this parameter.

PARTICIPANT: Approved as a participant for parameter.

COORDINATOR: Approved as a PT/ILC coordinator for the parameter.

ANALYST: Approved as PT/ILC analyst for the parameter.

REPORTS: Approved to develop reports under the supervision of the Technical Manager for the parameter.

Form 4: PT/ILC Feedback and Complaints

Page 1 of 1

Instructions: Use this form to record any complaint or pertinent communication received about NIST WMD's services as they apply to the conduct of PT/ILC activities. If the complaint or comment is received in writing, attach the complaint to this record. If the complaint or comment is received by telephone, fill out sections 4 and 5 completely.

1. Name of Person completing form	3. Check one of the following ☐ Complaint/communication received in writing – copy of documentation attached ☐ Complaint/communication received by telephone – was caller requested to send documentation? ☐ yes ☐ no
2. Date of receipt of complaint or communication	

4. If the complaint/communication was received by telephone, provide the following information:

Name and Address of person making complaint/communication

Phone number Fax number

5. If the compliant/communication was received by telephone, describe the issue:

6. Name of Responsible Manager:	
7. For Quality Manager Use Only	
Date Logged:	Complaint Number:
Date C.A.R. issued (if applicable):	Date Closed:

Form 5: WMD Quality System Management Review

Page 1 of 2

Date:	
Location:	
Personnel Present:	
Agenda	Record of Discussion, and Assigned Actions, and Estimated Completion Dates
Suitability and Effectiveness of Quality System	
Quality and Applicability of PT/ILC Activities	
RMAP Meeting Reports	
Report of Internal Audits	
Report of External Audits	
Client Feedback/Complaints	
Resources (Facilities, Standards, and Equipment)	

Form 5: WMD Quality System Management Review

Page 2 of 2

Outstanding Items from Previous Management Review	
Staff Training	
Other Reports	
Miscellaneous Topics	

Form 6: WMD Internal Audits for PT/ILC Activities

Page 1 of 3

PART A	
Dates of Assessment:	
Lead Assessor:	
Assessment Team Members:	
Quality System Review (all sections are assessed annually, though not necessarily at the same time)	
Section 1.1	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.2	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.3	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.4	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.5	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.6	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.7	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.8	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.9	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.10	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.11	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.12	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.13	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.14	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.15	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.16	☐ Assessed ☐ Conforming ☐ Nonconformities

Form 6: WMD Internal Audits for PT/ILC Activities

Page 2 of 3

Section 1.17	☐ Assessed ☐ Conforming ☐ Nonconformities
Section 1.18	☐ Assessed ☐ Conforming ☐ Nonconformities

PART B	
PT/ILC Quality System Review (Select a 10 % sample (minimum 1 per region) of PT/ILCs conducted each year and assess all elements of program)	
PT/ILC Region assessed:	
PT/ILC activity assessed:	
Section 2.1	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 3.1	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 3.2	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 3.3	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 4.1	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 4.2	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 4.3	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 4.4	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 4.5	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 5.1	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 5.2	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet
Section 5.3	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet

Form 6: WMD Internal Audits for PT/ILC Activities

Page 3 of 3

Section 5.4	☐ Conforming ☐ Nonconformities ☐ Not Developed Yet

PART C	
Audit for Closure of Previous Deficiencies	☐ Conforming ☐ Nonconformities
Attach all nonconformities and comments using the NCAP form and all other supporting documentation.	

Form 7: NIST WMD Nonconformance/Corrective Action/Preventive Actions (NCAP)

Page 1 of 2

1. Name of Person completing form:	3. Check one of the following:
2. Date:	☐ Nonconformity ☐ Preventive Action
4. Identification of Nonconformity or Preventive Action:	
5. Source of Discovery:	
6. Investigation Results:	
7. Root Cause:	
8. Evaluation of Significance:	
9. Action Required? ☐ Yes ☐ No	
10. Does PT/ILC need to be halted? ☐ Yes ☐ No	
11. If halted, identify location of Artifact/position in scheme:	
12. Action Taken:	
13. Due Date: Participant Notification (in writing):	
14. Name of Responsible Manager:	
15. Date PT/ILC Resumed (if applicable):	

Form 7: NIST WMD Nonconformance/Corrective Action/Preventive Actions (NCAP)

Page 2 of 2

16. For Quality Manager Use Only	
17. Due Date:	
18. Name of Responsible Manager:	
19. Date PT/ILC Resumed (if applicable):	
20. For Quality Manager Use Only	
Date C.A.R. issued (if applicable)	Event Number:
Date Closed:	
Follow-up Audit Information (as applicable):	

Form 8: Schedule & Shipping

(nonmandatory)*

Page 1 of 1

PT/ILC Identification:	
PT/ILC Coordinator:	

Scheduled Date	Laboratory	Date Shipped to:	Shipper	Tracking #	Date Received

* As long as the coordinator maintains a tracking system for the artifacts or standards, use of a form is not required.

APPENDIX B – PROCEDURES & POLICIES

Number	Title
1	Software Validation Procedure
2	Selection of Delegates Procedure (To be developed).
3	NISTIR 7082 PT/ILC Policy & Plan

Procedure 1: PT/ILC Software Validation Procedure

Background: All software that has been designed to perform computations associated with reporting, analyzing or evaluating acceptance criteria for PT/ ILC activities are required to be validated according to this procedure. Commercial software such as Microsoft Excel or MathCAD does not require validation, but worksheets created for PT/ILC activities do require validation.

1) Ensure that the Software contains the following information:
    a. Title of Software;
    b. Date of Latest Revision (kept within the electronic file);
    c. Identification information of person who performed the last revision.
    d. Document technical specifications used (i.e., specific formulas for air or water density, coefficients of expansions).

2) The Technical Manager or Designee performs the software validation. Under no circumstance is the author of the software to be evaluated allowed to perform the software validation.

3) All computational functions of the software are to be validated after each revision (and reviewed at least annually). Validation is accomplished by entering a data set into the software to be validated, and comparing the results obtained to results obtained by:
    a. Results published in a textbook or other appropriate reference for the dataset;
    b. Hand or calculator computations (which are documented);
    c. A program from a different software platform;
    d. A program on the same software platform that is significantly different from the software to be validated.

4) Document the validation method selected, password(s), and supporting information for the validation process.

5) Sign and Date the documents and submit them to the Technical Manager for final review and approval.

Procedure 2: Selection of Delegates

To be developed at a later date.

Policy: NISTIR 7082 "Proficiency Test Policy and Plan (for State Weights & Measures Laboratories)" (on-line at http://www.nist.gov/labmetrology)